



**WA Pharmacy Quality Assurance Commission
2020 Responsible Pharmacy Manager
Pharmacy Self-Inspection Worksheet
Nuclear Pharmacy Addendum**

Attention: Responsible Pharmacy Manager

Washington law holds the responsible manager and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this report within the month of March or within 30 days of becoming responsible manager (as required by WAC 246-945-005(4)) may result in disciplinary action. **The following addendum is required to be filled out and kept on file with the General Pharmacy Self-Inspection Worksheet. Do not send to the Commission office.**

The primary objective of this report, and your self-inspection, is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. **All radiopharmaceuticals must be compounded in accordance with RCW 18.64.270(2) which requires compliance with the U.S. Pharmacopeia (USP) standards for sterile and non-sterile compounding. You must also complete those self-inspection addendums.** (NOTE: Neither the self-inspection nor a Commission inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.)

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

Date responsible manager/change of responsible manager inspection was performed: _____

Signature of responsible pharmacy manager: _____

Questions highlighted in blue are questions that will be focused on during routine pharmacy inspections.

Compliant			#	Rule Reference	Notes/Corrective Action	
Yes	No	N/A				
General Requirements						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1.	Does the pharmacy have a permit to operate as a nuclear pharmacy?	WAC 246-945-490(1) “The commission shall issue a permit to operate a nuclear pharmacy providing radiopharmaceutical services to a qualified nuclear pharmacist. The qualified nuclear pharmacist shall: (a) Supervise all personnel performing tasks in the preparation and distribution of radiopharmaceuticals. (b) Be responsible for all operations of the licensed area. (c) Designate one or more qualified health care professionals licensed under the chapters specified in RCW 18.130.040, to have access to the licensed area in emergency situations and in the nuclear pharmacist's absence. These individuals may obtain radiopharmaceuticals for the immediate emergency and must document such withdrawals in the control system.”	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2.	Are all pharmacists working in the nuclear pharmacy qualified nuclear pharmacists or working under the supervision of a qualified nuclear pharmacists?	WAC 246-945-180 “To receive a nuclear pharmacist endorsement, a pharmacist must: (1) Be licensed to practice in Washington; (2) Meet minimal standards of training and experience in the handling of radioactive materials in accordance with WAC 246-240-075 and submit to the commission proof of compliance; and (3) Receive a letter of recognition as a nuclear pharmacist from the commission.”	
			3.	Does the pharmacy comply with USP chapters <795>, <797>, and <800> where	WAC 246-945-100 (1) “All licensees of the commission must comply, at a minimum, with the following chapters of	

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		applicable?	the United States Pharmacopeia (USP) when engaged in compounding nonsterile and sterile products for patient administration or distribution to a licensed practitioner for patient use or administration: (a) USP General Chapter <795>; Pharmaceutical Compounding - Nonsterile Preparations; (b) USP General Chapter <797>; Pharmaceutical Compounding - Sterile Preparations; (c) USP General Chapter <800>; Hazardous Drugs - Handling in Healthcare Settings; and (d) USP General Chapter <825>; Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging."	
Compliant			#	Rule Reference	Notes/Corrective Action	
Yes	No	N/A				
Facilities						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4.	Are areas where radiopharmaceuticals are prepared separate from nonradiopharmaceutical preparation areas?	WAC 246-945-490(2)(a) "Nuclear pharmacies shall have adequate space, commensurate with the scope of services to be provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals and shall be secured from access by unauthorized personnel.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5.	Are areas where radiopharmaceuticals are prepared secured from unauthorized personnel access?	WAC 246-945-490(2)(a) "Nuclear pharmacies shall have adequate space, commensurate with the scope of services to be provided. The nuclear pharmacy area shall be separate from the pharmacy areas for nonradiopharmaceuticals and shall be secured from access by unauthorized personnel. "	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6.	If needed, has the pharmacy submitted a waiver to the	WAC 246-945-490(2)(b)(c) "A nuclear pharmacy handling	

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Commission for exemption of space requirements?	radiopharmaceuticals exclusively may be exempted from the general space requirements for pharmacies by obtaining a waiver from the commission; and (c) Detailed floor plans shall be submitted to the commission and the state radiation control agency before approval of the pharmacy license."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7.	Does the pharmacy have adequate equipment to prepare radiopharmaceuticals?	WAC 246-945-492(1) "A nuclear pharmacy shall have adequate equipment appropriate with the scope of radiopharmaceutical services to be provided. The nuclear pharmacy shall submit to the commission and the radiation control agency a detailed list of equipment and description of use before approval of the license."	
Compliant			#	Rule Reference	Notes/Corrective Action	
Yes	No	N/A				
Radiopharmaceutical Product and Recordkeeping						
NOTE: The Pharmacy Quality Assurance Commission (Commission) is not currently requiring pharmacies to comply with USP General Chapter <825>; Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging (USP <825>). For further information, please contact the Commission's office at WSPQAC@doh.wa.gov.						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8.	Does the nuclear pharmacy comply with USP <825>?	WAC 246-945-490(3) "A nuclear pharmacy shall prepare, compound, and dispense radiopharmaceuticals in accordance with USP <825>"	Full compliance with USP <825> is not currently required. For further information, please contact the Commission's office at WSPQAC@doh.wa.gov.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9.	Does the final drug product meet USP <825>?	WAC 246-945-490(4) "The preparation of nuclear pharmaceuticals requires the compounding skills of the nuclear pharmacist and shall be done to assure that the final drug product meets USP <825>"	Full compliance with USP <825> is not currently required. For further information, please contact the Commission's office at WSPQAC@doh.wa.gov.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10.	Do you have acquisition and deposition records of all your radiopharmaceuticals?	WAC 246-945-490(5) "A nuclear pharmacy shall maintain records of acquisition and disposition of all radiopharmaceuticals in accordance with applicable regulations of the	

					commission, the state radiation control agency and other state and federal agencies."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11.	Are radiopharmaceuticals dispensed based on valid prescriptions or orders from practitioners authorized to possess and administer them?	WAC 246-945-490(7) "Radiopharmaceuticals are to be dispensed only upon a prescription from a practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners. In absence of a prescription for an individual identified patient, the statement "Office Use Only" should be applied."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12.	Are radioactive materials transferred to other authorized persons?	WAC 246-945-490(8) "A nuclear pharmacist may transfer to authorized persons radioactive materials not intended for drug use, in accordance with regulations of the state radiation control agency."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13.	In addition to labeling requirements in RCW 18.64.246, are the immediate outer containers of the radiopharmaceuticals dispensed labeled with the following?	WAC 246-945-490(9) "In addition to labeling requirements of WAC 246-945-015 through 246-945-017 for nonradiopharmaceuticals, the immediate outer container of the radiopharmaceutical to be dispensed shall also be labeled with: (a) Standard radiation symbol;(b) The words "caution-radioactive material";(c) Radionuclide and chemical form (generic name);(d) Activity dispensed with units (millicuries or microcuries) at calibration date and time;(e) If a liquid, the volume in milliliters;(f) Calibration date and time for the dose; (g) BUD and special storage and	
			a.	Standard radiation symbol		
			b.	"Caution-radioactive material"		
			c.	Name of radiopharmaceutical		
			d.	Amount of radioactive material contained, in millicuries or microcuries		
			e.	If applicable, amount of liquid contained in		

				milliliters	handling instructions for nonimmediate use;(h) Specific concentration of radioactivity; and(i) The patient name/identifier, and number of dosage units dispensed, for all therapeutic and blood-products."	
			f.	Calibration time and date		
			g.	Expiration data and storage		
			h.	Specific concentration of radioactivity		
			i.	Patient name/identifier and number of dosage units		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14.	In addition to labeling requirements in RCW 18.64.246, are the immediate outer containers of the radiopharmaceuticals dispensed labeled with the following?	WAC 246-945-490(10) "The immediate container of the radiopharmaceutical to be dispensed shall be labeled with:(a) The standard radiation symbol;(b) The words "caution-radioactive material";(c) The name of the nuclear pharmacy;(d) The prescription number;(e) Radionuclide and chemical form (generic name);(f) The date;(g) Activity dispensed with units (millicuries or microcuries) at calibration date and time; and(h) The patient name/identifier for all therapeutic and blood-products."	
			a.	Standard radiation symbol		
			b.	"Caution Radioactive material"		
			c.	Pharmacy name		
			d.	Prescription number		
			e.	Name of radiopharmaceutical		
			f.	Date		
			g.	Amount of radioactive material contained, in millicuries or microcuries		
			h.	Patient name/identifier		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15.	Is there a radiometric method used for determining the amount of radioactivity for each radiopharmaceutical preparation?	WAC 246-945-490(11) "The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing."	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16.	Are current state radiation control laws and regulations readily available?	WAC 246-945-490(13) "The nuclear pharmacy shall have readily available the current applicable state laws and regulations of the commission and state radiation control agency."	

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17.	Are research resources for the radiopharmaceutical services provided by the pharmacy available?	WAC 246-945-490(14) “The nuclear pharmacy shall maintain, and submit to the commission and state radiation control agency, a library commensurate with the level of radiopharmaceutical service to be provided before approval of the license.”	
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